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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,334	03/09/2000	Ry Wagner	4257-0018.30	3299

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/03/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/522,334

Applicant(s)

WAGNER ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16, 17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16, 17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 22 April 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/522,334 is acceptable and a CPA has been established. An action on the CPA follows.

STATUS OF THE APPLICATION

2. Claims 12, 14, 15 and 18 have been cancelled without prejudice.
3. Claims 20-23 have been added.
4. The rejection of claim 18 under 35 U.S.C. § 112, first paragraph, is now moot in view of Applicant's cancellation of said claim.
5. The rejection of claims 14 and 15 under 35 U.S.C. § 112, second paragraph, is now moot in view of Applicant's cancellation of said claims.
6. The rejection of claims 1-11 and 16, 17 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Hayashi *et al* (Science 1992, 258:1350-1353) in view of Schell *et al* (The Plant Journal 1999, 17(5):461-466) is withdrawn in view of Applicant's amendments to the claims. Claims 12, 14, 15 and 18 have been cancelled.

Drawings

7. While the Draftsman has approved the drawings as originally filed, the Examiner objects to figures 9A, 9B, 10A and 10B, because there is no reference to the SEQ ID NO in either the figure or the description of said figures on page 5 of the specification. Accordingly the instant application is not in compliance with the Sequence Rules. New formal drawings are required in this application or the specification must be amended to

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properly disclose the illustrated nucleotide or polypeptide sequences. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claims 1 and 20 are objected to because of the following informalities: At line 4, the phrase "*E. coli* origin or replication" appears to be a typographical error which should read -- *E. coli* origin of replication --. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 19 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a transgenic fleshy fruit-bearing plant comprising enhanced expression of a gene identified by the method of claim 1.

Applicant describes genes isolated by the method of claim 1, said genes being isolated from *Lycopersicon esculentum* (tomato) (see pages 23-25 of the specification).

Applicant does not describe any transgenic fleshy fruit-bearing plants.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

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and 19

11. Claims 1-11, 16 and 17¹ are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of promoter activation tagging of tomato, does not reasonably provide enablement for a method of promoter activation tagging of any fleshy fruit-bearing plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a method for identifying genes associated with a desired trait in a fleshy fruit-bearing plant comprising transforming cells of said plant with a vector comprising an enhancer and a selectable marker-encoding nucleotide sequence, selecting plant cells which have been transformed, regenerating transformed plant cells to yield mature plants and selecting plants having a desired trait.

Applicant teaches a method of identifying genes associated with a desired trait using a promoter activation tagging method using tomato.

Applicant does not teach a method of identifying genes associated with a desired trait using said method using any other fleshy fruit-bearing plant.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance in practicing the claimed method, only providing guidance to practicing said method using tomato. The claimed invention comprises several critical method steps for which extensive guidance is required, in order to practice said method within the full scope of the claims.

The first critical method step is regenerating transformed plant cells to yield mature plants. The art teaches that plant transformation remains an art because of the unique conditions required for each crop species and to accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one (see Hanson and Wright 1999, Trends in Plant Science 4(6):226-231, in particular page 230, right column, 1st paragraph). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to adapt or create transformation methods to regenerate transformed plant cells to yield mature plants for all fleshy fruit-bearing plants as broadly claimed.

The second critical feature is the plant cell expression vector comprising an enhancer. Applicant has provided limited guidance for practicing the claimed method as broadly claimed. The art teaches that fleshy berry fruit plants have different structure, metabolism and development compared to silique plants, such as *Arabidopsis*, and probably have some unique sets of regulatory elements (see Meissner *et al* 2000, The Plant Journal 22(3):265-274, specifically the paragraph spanning pages 271-272). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to adapt or create a myriad of plant cell

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expression vectors comprising an enhancer to transform a myriad of fleshy fruit-bearing plants to practice the invention as broadly claimed.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 8, 9, 10, 17 and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jones *et al* (1994, Science 266:789-793) taken with the evidence of Jones *et al* (1992, Proceedings of the Royal Society of Edinburgh, 99B (3/4) pages 107-119).

Jones (1994) discloses a method of identifying genes associated with a desired trait in tomato, that being pathogen resistance, comprising transforming a tomato plant with a plant cell expression vector, selecting plant cells which have been transformed by their ability to grow in the presence of an amount of selective agent that is toxic to non-transformed plant cells, regenerating transformed plant cells to yield mature plants, select plants having a desired trait and identifying, isolating and characterizing the Cf-9 gene the transcription of which was enhanced (see Figure 2 on page 790). Jones (1992) discloses the method of transposon tagging used by Jones (1994) wherein tomato plants are transformed using *Agrobacterium* mediated transformation methods comprising a plant cell expression vector having a kanamycin selection marker gene, and that herbicide resistance marker genes may also be used (see page 110). The

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terms "enhance" and "enhancer" are subjective. One of skill in the art at the time of Applicant's invention would have recognized that the method of Jones would work as an enhancer, if the transposon functioned to disrupt a repressor region within a plant genome, thus activating transcription of plant DNA from a nearby promoter as described by Applicant on page 5, lines 39-41 of the specification. Hence, Jones has previously disclosed all of the claim limitations.

14. Claim 19 is rejected under 35 U.S.C. § 102(b) as being anticipated by Giovannoni *et al* 1989 (The Plant Cell, 1:53-63).

Giovannoni discloses a transgenic tomato plant comprising enhanced expression of a polygalacturonase gene isolated from tomato, wherein said gene is associated with the fruit characteristic of increased uronic acid and decrease in pectin cell wall components upon ripening. The tomato polygalacturonase gene of Giovannoni was isolated using a subtraction cDNA library method (see page 54, right column, last paragraph). Hence, Giovannoni has previously disclosed all of the claim limitations. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-11, 16, 17 and 19-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Walden *et al* 1994 (Plant Molecular Biology 26:1521-1528) in view of Jones *et al* 1992 (Proceedings of the Royal Society of Edinburgh, 99B (3/4) pages 107-119).

Walden teaches a method of identifying and isolating genes implicated as playing a role in plant growth and development in tobacco comprising transforming plant cells with a plant cell expression vector having an *E. coli* origin of replication, a 4X tandem 35S promoter, a kanamycin selectable marker-encoding nucleotide sequence operably linked to a promoter and a transcription termination element, and a T-DNA sequence, using an *Agrobacterium* transformation method (see Fig. 1 on page 287).

Walden does not teach said method using a fleshy fruit-bearing plant, such as tomato, specifically. Nor does Walden teach said method using all of the claimed enhancers, an herbicide resistance gene or a dwarf plant.

Jones teaches a method of identifying and isolating genes implicated as playing a role in plant growth and development in tomato, a fleshy fruit-bearing plant, comprising a transposon tagging method, wherein said method uses either kanamycin or Basta resistance genes as the selectable marker (see page 110). In addition, Jones teaches that the method functions similarly in tobacco and tomato, said method being adapted from known methods in tobacco to be used in tomato (see page 110, 1st paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Walden, of a method of promoter activation tagging using a 4X tandem 35S promoter construct, to identify and isolate genes in tomato in view of the teachings of Jones. Jones teaches that transposon tagging operates similarly in both tobacco and tomato, and in fact the plant cell expression vectors used for either plant are functionally similar. Walden teaches that the advantages of promoter activation tagging, over that of say transposon tagging, is that one is selecting for dominant mutations that are more readily identified (see page 1526, right column, 3rd paragraph). Given the success of Walden in identifying genes associated with a desired trait in tobacco using promoter activation tagging, one of ordinary skill in the art would have had a reasonable expectation of success in using the method of Walden to identify genes associated with a desired trait in tomato.

In reference to the listed enhancers in claims 3-7, the use of a dwarf plant or a dwarf tomato plant at claims 11 and 23, and the specific transformation methods for tomato cited in claims 21 and 22, the following arguments are put forth. Applicant admits that enhancers of gene transcription, in particular promoters, were well known in the art at the time of Applicant's invention, that would operate in tomato, for example (see page 13 of the specification). It is unclear from the instant specification if the use of a dwarf tomato plant to practice the instant invention is an inventive step, leading to the teaching of unexpected results. In addition, the specific transformation methods for tomato cited in claims 21 and 22 do not appear to be critical features of the claimed invention, in fact Applicant teaches using a leaf transformation method at page 22 of the

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specification, and methods well known in the art at the time of Applicant's invention for transforming tomato. Hence it is unclear from the instant specification where the examples of unexpected results are taught in relation to the instant claims. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of non-obviousness should be commensurate with the scope of the claims.

Conclusion

17. No claims are allowed.

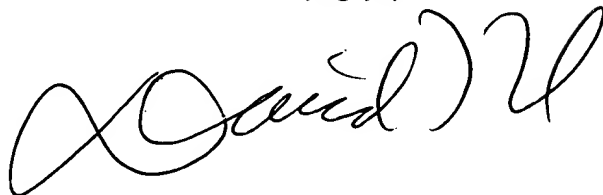
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.
28 June 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and title of the Primary Examiner.